EXAMPLE EXPOSURE ASSESSMENT FOR CHEMICAL C

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Prepared by:
Inert Manufacturers Inc.
226 Hive St.
Honeywell, CA 00000

Project Team:
Dr. Edgar Bee, Inert Manufacturers
Dr. J. Doe, The Framis Factory
M.A. Diet, Pesticide Formulators Inc.

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EXECUTIVE SUMMARY

The purpose of this document is to provide an estimation of human exposures to Chemical C that may have relevance to the health of children. In an attempt to produce a complete documentation of relevant exposures, all known uses of Chemical C were considered, and potential pathways of exposure were determined. Information relating to those pathways and routes of exposure was gathered from various sources (e.g., internal study reports prepared by Inert Manufacturers Inc. and Pesticide Formulators Inc., data found in the scientific literature, etc.). Chemical C is manufactured at Inert Manufacturers Inc. and is processed as the inert (other) ingredient in the pesticide product, Pest-X. The volume assessed in this submittal represents the only two uses of the chemical, as sold by Inert Manufacturers Inc. Pest-X is used at numerous households as an insecticide. Chemical C has also been detected in groundwater, so this route of exposure was also considered.

Worker exposures to Chemical C were considered because of the exposure of female employees during manufacturing, and the potential resulting exposure to their children. Modeling has been conducted to assess the exposure that can occur to infants who consume the breast milk of women who work in the manufacturing facility for 8 hours per day. Exposure to infants of nursing mothers who work at the manufacturing facility has been estimated to be as high as 0.025 mg/kg/day.

The public, including children, is potentially exposed to Chemical C from air and water releases during manufacturing. No monitoring data have been collected for surface water releases, and no direct monitoring data were obtained linking releases from the manufacturing or use of Chemical C to exposure from incidental inhalation among local residents. However, estimates of exposure from ground water studies are believed to represent reasonable-to-high exposure estimates for water releases. Soil releases are minimal and therefore no significant exposure is expected for children from that pathway. The results from EPA's Industrial Source Complex-Long Term (ISCLT) model were used to estimate potential exposures to the general population from fugitive air emissions from manufacturing. Potential exposure of the adult general public from fugitive air emissions from manufacturing has been estimated as $1.36\text{x}10^{-05}$ µg/kg/day, based on the ISCLT model. Data are currently being collected that will allow for a more accurate estimate of fugitive releases. These data will be used to evaluate the ability of the model to estimate downwind concentrations, which, in turn, may allow the company to better estimate exposures to the general population. If validated by air monitoring data, this pathway may be eliminated as a significant source of exposure, particularly when compared to acute exposure from consumer uses.

In a study of potential exposures to workers from indoor air releases of Chemical C, inhalation exposure among processors was very low (i.e., Chemical C was not detected in any personal monitoring device). Dermal exposure was not expected because processing occurs via a closed system that is fully automated and therefore eliminates the need to handle the material manually.

Potential residential exposures to Chemical C could occur from the use of Pest-X (containing Chemical C) for indoor crack and crevice treatments (i.e., inhalation and dermal during consumer application, and inhalation, dermal, and, non-dietary ingestion after application). These potential exposures have been evaluated via a combination of monitoring and modeling assessments. Dermal acute potential dose rate (APDR) estimates among adult handlers (i.e., applicators) ranged from 0.009 to 0.017 mg/kg/day. Average daily dose (ADD) among this group ranged from 2.8×10^{-4} to 5.6×10^{-4} mg/kg/day. Inhalation exposures were very low (i.e., 7.1×10^{-7} to 1.4×10^{-6} mg/kg/day [APDR]; 2.4×10^{-8} to 4.7×10^{-8} mg/kg/day [ADD]). Postapplication dermal exposure among children was estimated to be 0.4 mg/kg/day (APDR and ADD). Non-dietary ingestion exposure was 0.13 mg/kg/day (APDR) and 0.063 mg/kg/day (ADD) and inhalation exposures were below detection limits within 1 hour after application. There are no anticipated exposures to Chemical C among commercial applications because Pest-X is not labeled for use by professional commercial applicators.

Exposure from drinking water was assessed based on monitoring data from groundwater. These data are not associated with a specific release, but may be related to non-point sources of undetermined origin. Based on a national groundwater study conducted by DoD, acute exposure to Chemical C from ingestion of groundwater among 3-year old children was estimated to average 0.017 µg/kg/day. Chronic exposure was estimated to be 0.0067 µg/ kg/day. A first-tier estimate of an aggregate exposure for children was also assessed to account for dietary and non-dietary ingestion, dermal, and inhalation exposures. The aggregate acute exposure (i.e., from multiple sources) to Chemical C was estimated to be 0.53 mg/kg/day for 3-year old children. Aggregate chronic exposure was 0.46 mg/kg/day. All of the exposure estimates for this assessment were based on conservative or median- to high-end values and are therefore considered high-end screening estimates only. Further characterization of exposure estimates may be found in the discussion of the individual pathways and aggregate exposure scenarios. These estimates may be useful for comparison to toxicity reference doses in the Tier 1 risk assessment.

1. INTRODUCTION

Chemical C is a chemical in commerce that is manufactured by Inert Manufacturers Inc. and sold to Pesticide Formulators Inc. to formulate the pesticide product Pest-X. Chemical C is an inert ingredient in Pest-X. Pest-X is used in numerous households as an insecticide. This exposure assessment was developed by Inert Manufacturers Inc., in cooperation with Pesticide Formulators Inc. The Framis Factory provided technical support for the modeling efforts undertaken to assess general population exposures from fugitive air emissions from the manufacturing process. The objectives of this exposure assessment document are:

- to identify and evaluate the potential pathways of exposure relevant to children;
- to consolidate the exposure information that has been generated for Chemical C; and,
- to estimate the potential exposure of children to Chemical C using the available use information, exposure data, and any other resources available, such as models.

Information from multiple sources (e.g., internal study reports prepared by Inert Manufacturers Inc. and Pesticide Formulators Inc., data found in the scientific literature, etc.) has been reviewed and summarized in this document.

2. GENERAL INFORMATION

This section presents background information on the chemical identity and the chemical-physical properties of Chemical C. Subsection 2.1 discusses the physical form, molecular formula and structure, and other names by which Chemical C is known. Subsection 2.2 provides a compilation of the chemical and physical properties of Chemical C that influence its behavior in the environment. Subsection 2.3 provides information about the environmental fate and transport of Chemical C.

2.1 Chemical Identity

Chemical C (CAS No. 1111-00-1), is a colorless, clear liquid. It is an aromatic hydrocarbon with a framis group. The chemical formula is HO-C_6H_3( )-OH, and the structure is provided below.
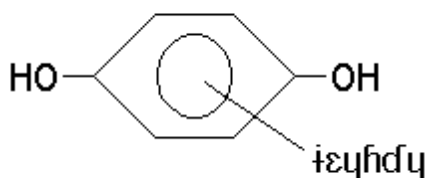
Structure of Chemical C

Chemical C is also known by the following names: chem-X and diphenyl-X.

2.2   Chemical and Physical Properties

The chemical and physical properties of Chemical C, gathered from several references, are presented in Table 1.

Table 1. Chemical and Physical Properties of Chemical C

Property	Condition/Comment	Value	Reference
Molecular Weight (MW)	-	220 g/mole	Merck, 1989
Melting Point	-	-15°C	Merck, 1989
Boiling Point	742 mm Hg 760 mm Hg 760 mm Hg	115°C 119°C 120°C	Verschueren, 1983 Verschueren, 1983 Merck, 1989
Density	25°C	1.6 g/mL	Merck, 1989
Vapor Pressure (VP)	25°C	5.0×10^{-4}	Merck, 1989
Water Solubility (S)	20°C 25°C 35°C	98 mg/L 120 mg/L 160 mg/L	Loo et al., 1995 Merck, 1989 Merck, 1989
Log Octanol-water Partition Coefficient (K_{ow})	experimental experimental	3.2 3.6	Scott, 1992 Green, 1994
Henry's Law Constant (H)	experimental theoretical atm-m^3/mole atm-m^3/mole 1.2×10^{-6} 2.3×10^{-6}		Green, 1994 Calculated at 25°C as H = [Vp (mm-Hg) x MW (g/mole)] / [S (mg/L) x 760 (mm/atm)
Adsorption Coefficient (K_{oc})	clay soil	398	Green, 1994
Photolysis	½ life	23 days	Howard, 1990

Hydrolysis	½ life	10 days	Howard, 1990
Biodegradation	½ life (water)	15 days	Howard, 1990
Transport/distribution	theoretical	soil water sediment air	80% 5% 10% 5%

2.3   Environmental Fate and Transport

Little empirical data were found regarding the transport and partitioning of Chemical C in the air. In the atmosphere, Chemical C should exist primarily as a vapor and not adsorb to suspended particulates (Loo et al., 1995). The water solubility of 120 mg/L (Merck, 1989) indicates that at least partial removal of Chemical C from the atmosphere will occur by wet deposition. The transport of Chemical C from water to air can occur due to volatilization. However, such volatilization will be very slow, as indicated by Chemical C's low Henry's Law Constant of 1.2 x 10^{-6} atm-m^3/mole .

Adsorption to particulate matter will transport Chemical C from water to suspended solids and sediment in the water (Green, 1994). The estimated soil adsorption coefficient (K_{oc}) for Chemical C is 398 (Green, 1994), which suggests moderately strong adsorption to soil. This suggests that Chemical C in the water column adsorbs moderately to suspended solids and sediments. Therefore, volatilization from soil is not expected to be an important transport process (Green, 1994). Likewise, leaching and runoff from soil will be relatively minor processes (Green, 1994). However, based on a national groundwater study conducted in 1995, Chemical C was detected at low levels in 486 of 563 groundwater samples collected across the United States. No information was found on the bioconcentration or biomagnification of Chemical C through aquatic or terrestrial food chains. Because of its moderate water solubility, Chemical C in soil (for example, landfills) has the potential to migrate into groundwater. The relatively frequent detection of Chemical C in groundwater confirms its mobility in soils. Biodegradation in soil and groundwater is thought to be slow (half-life on the order of months to years).

3.   SOURCES AND RELEASES

Information on the sources and releases of a chemical is necessary to understand potential exposure pathways and to estimate exposures. This section provides estimates of releases from the manufacturing by Inert Manufacturers Inc., and processing of Chemical C by Pesticide Formulators Inc. to formulate the pesticide Pest-X. Releases of Chemical C are also estimated for sites that use Pest-X as an indoor residential insecticide. The volume assessed in this submittal represents the

Areas of the facility where the product is handled (e.g., storage tank to truck transfer stations) are well ventilated to protect the workers from prolonged exposure to chemical vapors.

Releases from the manufacturing site includes air emissions and liquid waste from clean-up operations. It is estimated that about 1,000 lbs of Chemical C per year over 250 days were emitted (including 900 lb of fugitive and 100 lb stack emissions). The estimate is derived based on published emission factors for a very similar process, the manufacturing process of Chemical Cy, which is very analogous in structure to Chemical C, and also is manufactured using identical unit operations (i.e., equipment). The emission factors can be found in Environmental Release and Exposure Assessment of Chemical Cy by Joe Chemist, 1998. No air monitoring has been conducted for this facility. The total amount of clean-up waste, which is treated as hazardous waste, is estimated at 10,000 lbs/year, which contains about 100 lbs/year of Chemical C. The facility also generates other hazardous wastes that do not contain Chemical C. The amount of solid waste is also estimated based on data obtained from Joe Chemist (1998). The hazardous waste is sent off-site to a RCRA Subtitle C location.

3.2   Processing

Chemical C is delivered in trucks to Pesticide Formulators Inc. where it is unloaded via pump to a mixing vessel which is then where it is processed into the formulated product (Pest-X) at a concentration of 50% pesticide and 50% liquid inert ingredients (Chemical C). The Pesticide Formulators facility is located at 0 Fairfax Street, New City, New Jersey. It is one of the ten sites in the United States where Chemical C is processed. Formulation involves dilution of proprietary pesticide ingredients with Chemical C and water to make a 50% emulsifiable concentrate. The formulation process uses a closed system in which the pesticide and Chemical C are mixed with water that enters through a pump. Likewise, packaging of the product occurs via a closed, mechanized system. Pest-X is packaged in bulk containers (totes) which are subsequently transported to customer sites in trucks. Also, because a closed pumping system is used, spills resulting in dermal exposure are unlikely. Each year 1,000,000 pounds of Chemical C is used to formulate Pest-X for indoor insecticide use. A diagram of the processing of Chemical C to formulate Pest-X is presented below. Approximately 1,000,000 pounds of Chemical C are processed per year by Pesticide Formulators Inc.

Chemical C may also be released from non-point sources as a result of percolation to groundwater from landfills and subsequent transport, and other mechanisms. A National groundwater study was conducted by the Department of Defense (DoD) to address these concerns.

4. REGULATORY REQUIREMENTS

Inert Manufacturing Inc. reports its releases (in lbs) annually under the TRI reporting, is a full quantity generator under the RCRA regulations, and is covered by the MACT air emission regulations. Facility operators comply with OSHA health and safety protocols. Employees that are exposed to Chemical C at the facility during the performance of their duties wear clothing that fully covers the skin (i.e., long pants and long sleeve shirts). To prevent prolonged skin surface exposure, the facility also provides PVC gloves. Employees that are exposed to the solid waste sludge generated by the facility during the performance of their duties wear similar clothes, in addition to respirators provided by the company. Skin should be washed promptly when contaminated. Likewise, Pesticide Formulators Inc. report releases under TRI and comply with OSHA regulations. Because a closed mixing and closed mechanized packaging system are used during processing, personal protective equipment is not required. The occupational and Federal environmental standards to which Inert Manufacturing Inc. and Pesticide Formulators Inc. comply are provided in Table 2. TRI reporting data for these 2 facilities are summarized in Appendix A.

Table 2. Occupational and Federal Standards

Threshold Limit Value	100 ppm
Permissible Exposure Limit	10 ppm
Short Term Exposure Limit	50 ppm
Toxic Release Reporting Required	Yes
Hazardous Air Pollutant	Yes
Clean Water Act priority Pollutant	No
RCRA U & P Waste	UUUU
Safe Drinking Water Act Contaminant	No
CERCLA Reportable Quantity	1 lb

The product containing Chemical C is labeled for residential use under FIFRA. The label provides the recommended uses, application rates (e.g., Pest-X, containing 50% Chemical C, should be

diluted 1:10 in water; 0.005 lb ai/100 ft^2 to treat a 100 ft^2 room), timing of application (e.g., once per month), and recommended application equipment. It also provides information on safety hazards and storage.

5.   POTENTIAL EXPOSURES

Potential exposure could occur from manufacturing or processing Chemical C, or from the use of Pest-X, which contains Chemical C. This section discusses the potential exposures that were addressed in this assessment. More detail on how each of the exposure estimates was generated are provided in the sections on monitoring and modeling. Both acute exposures and chronic exposures are calculated. For acute exposures, the Acute Potential Dose Rate (APDR) is estimated. It is a one day exposure. For chronic exposures, the Average Daily Dose (ADD) is estimated. The ADD is the estimated average daily dose over the period (e.g. years) of exposure.

Potential exposure could occur among workers or the general population residing in the vicinity of the manufacturing facility.   Inhalation is the most likely route of exposure. Concentrations of Chemical C in the wastewater from the facility have not been modeled or monitored. Ambient air concentrations downwind of the manufacturing facility have not been monitored for Chemical C. However, EPA's ISCLT model has been used to estimate ambient air concentrations. Data are currently being collected that will allow for a more accurate estimate of fugitive releases. These data will be used by the model to estimate downwind concentrations, which, in turn, may provide better exposure estimates to the general population. Potential exposures to infants has been documented related to the consumption of breast milk of women who work in the manufacturing facility for 8 hours per day. Table 3 presents a summary of the exposures assessed in this document.

Table 3. Occupational and General Population Exposure Summary from Manufacturing

Scenario	Exposure		Number of Persons Exposed	Maximum Duration	
	APDR mg/kg/day	ADD mg/kg/day		Hours/day	Days/year
a. infants of working mothers	0.003 - 0.025	0.003 - 0.025	4	NA	365
b. air release (environment)	1.36×10^{-7} (maximum dose)		4,000 (estimate of local population)	24	365

During the processing of Chemical C, there are potential exposures to workers from air releases of Chemical C. These exposures have been assessed based on data from Pesticide Formulators Inc (Pesticide Formulators, 1998). Also, there are potential exposures to the public from air and water releases. Although inhalation exposure of the general public has been estimated using a model (see Section 7.1), exposures from air and water releases from the processing facility have not been fully assessed and release data are currently being collected that would allow estimation of exposures to the general population, and hopefully validate the modeled exposures. Dermal exposures during normal operations are considered minimal based on extensive employee training in utilizing a closed system (interlocking hose connectors for bulk containers) and a fully automated, enclosed manufacturing process that virtually eliminates dermal exposure. Table 4 presents a summary of the assessed exposures from processing.

Table 4. Occupational Exposure Summary from Processing

Scenario	Exposure		Number of Persons Exposed	Maximum Duration	
	APDR mg/kg/day	ADD mg/kg/day		Hours/day	Days/year
a. Inhalation of Indoor Air	$< 7.0\times10^{-6}$	$<5.0 \times 10^{-6}$	15 (estimated number of workers in processing facility)	8	250

Exposure to Chemical C can occur as a result of dermal contact and inhalation among adults during handling of the Pest-X product (i.e., mixing, loading, and applying). Postapplication inhalation, dermal, and non-dietary ingestion exposures among residents may also occur. Inhalation exposures have been evaluated via monitoring studies. Dermal and hand-to-mouth exposures have been evaluated via modeling. Finally, exposure to Chemical C may occur via ingestion of groundwater containing residues from non point sources. The results of a national groundwater study provide data that may be used in estimating these exposures among the general population. Table 5 presents a summary of the assessed exposures from use of Chemical C in Pest-X.

Table 5. Consumer Exposure Summary from Residential Use of Crack and Crevice Product

Scenario	Exposure		Number of Persons Exposed	Maximum Duration	
	APDR mg/kg/day	ADD mg/kg/day		Hours/day	Days/year
a. Inhalation of indoor residues during application (adult)	7.1×10^{-7} to 1.4×10^{-6}	2.4×10^{-8} to 4.7×10^{-8}	~10,000	0.5	12
b. Dermal contact with indoor residues during application (adult)	0.009 to 0.017	2.8×10^{-4} to 5.6×10^{-4}	~10,000	NA	12
c. Inhalation of indoor residues post-application (child)	$<3.0\times10^{-6}$	$<3.0\times10^{-6}$	~20,000	24	365
d. Dermal contact with indoor residues postapplication (child)	0.4	0.4	~20,000	4	365
e. Non-dietary ingestion of indoor residues post-application (child)	0.13	0.063	~20,000	4	365

Some populations may be exposed to Chemical C via more than one route of exposure. For example, children may be exposed to Chemical C in indoor environments from residential treatments with Pest-X. They may also be exposed to Chemical C via dietary intake and the consumption of contaminated groundwater. This exposure assessment considers all of the potentially exposed populations and the estimated daily exposures for adults, infants, and small children. A study prepared by Inert Manufacturers estimated aggregate exposures for all populations and found that small children ("toddlers," or children 1-4 years) were the most sensitive population, in dose per body weight. A modeling approach was used to estimate total exposure from multiple sources.

6.   MONITORING DATA

This section presents the available monitoring data, and the exposure estimates generated from this monitoring data for this assessment, for Chemical C. The monitoring data in this section have been organized according to the sources of exposure. Section 6.1 provides monitoring data for manufacturing. Section 6.2 provides monitoring data for processing. Section 6.3 provides monitoring data for use of Pest-X (containing Chemical C) in indoor residential settings. Section 6.4 provides a summary of the monitoring data collected as part of the National Groundwater Study, and Section 6.5 provides information on ongoing monitoring study that will provide additional information on Chemical C in the future.

6.1   Concentrations of Chemical C in Breastmilk of Women in a Manufacturing Plant

In 2001, a study was conducted by The University of Important Study to evaluate potential exposures to Chemical C among nursing mothers working in our Chemical C manufacturing plant (University of Important Study, 2001). The objective of both the monitoring study and the resulting exposure assessment was to assess infant exposures, whose mothers work at the Chemical C manufacturing plant, to Chemical C in breast milk. The study collected breast milk samples from 4 nursing mothers and analyzed them for Chemical C.

To collect samples that would be representative of the average working mother, all of the women who worked at our Chemical C manufacturing plant during 2000 and 2001 were approached to take part in this study. A total of 4 nursing mothers agreed to participate.

All of the women were involved in production activities (e.g., monitoring and adjusting the mixing tanks, recording data from metering devices and other record keeping functions, cleaning,

packaging, and maintenance activities). The 4 women ranged in age from 19 to 28 years, with experience levels ranging from <1 year to 7 years. Specific information for each participant is presented in the table at the end of this section.

Single breast milk samples were collected from each of the 4 women who participated in the study. Samples of approximately 50 mL were collected from each woman at the end of a typical working day. Samples were collected, stored, and shipped to the laboratory at 4°C. Sample chain of custody forms were used to track samples.

SW 846, Method XXXX was used to analyze the samples. (U.S. EPA, 1986a). Analyses were performed by ABC Laboratories in Main Town, PA. The data collected during the monitoring study were screened for use in this exposure assessment. Quality assurance objectives were outlined in a Quality Assurance Project Plan that was prepared as part of the study and before any of the sampling began (University of Important Study, 2001). The Plan outlined the QA/QC procedures that were followed by the laboratory. To check the validity of the results from the lab, a single blind duplicate was submitted. All quality control procedures have been employed and are documented in an Appendix to the report.

The breast milk samples from the 4 volunteers contained concentrations ranging from 0.03 to 0.26 mg/L Chemical C with a mean of 0.11 mg/L over the 4 samples. Specific sample results for each participant are presented in the table at the end of this section.

Based on the sample results, Chemical C intake for infants was estimated to range from 0.003 to 0.025 mg/kg/day. Exposure to infants was estimated as follows:

$$APDR = C \times CR / BW$$

where:

APDR	=	acute potential dose rate (mg/kg/day);
C	=	concentration of Chemical C in Breast Milk (0.03 to 0.26 mg/L);
CR	=	consumption rate (0.7 L/day); and
BW	=	body weight (7.2 kg).

Thus, the range of the acute potential dose rate is:

$$\text{APDR} = 0.003 \text{ mg/kg/day} = (0.03 \text{ mg/L}) \times (0.7 \text{ L/day}) / (7.2 \text{ kg}), \text{ and}$$
$$\text{APDR} = 0.025 \text{ mg/kg/day} = (0.26 \text{ mg/L}) \times (0.7 \text{ L/day}) / (7.2 \text{ kg})$$

The ADD was then calculated as:

$$\text{ADD} = \text{APDR} \times \text{EF} \times \text{ED} / \text{AT}$$

where:

ADD	=	average daily dose (mg/kg/day);
EF	=	exposure frequency (365 days/year);
ED	=	exposure duration (1 year); and
AT	=	averaging time (1 year x 365 days/year).

Thus, the range of the average daily dose is:

$$\text{ADD} = 0.003 \text{ mg/kg/day} = (0.003 \text{ mg/kg/day}) \times (365 \text{ days/yr}) \times (1 \text{ yr}) / (1 \text{ yr} \times 365 \text{ days/yr})$$

$$\text{ADD} = 0.025 \text{ mg/kg/day} = (0.025 \text{ mg/kg/day}) \times (365 \text{ days/yr}) \times (1 \text{ yr}) / (1 \text{ yr} \times 365 \text{ days/yr})$$

For this scenario, the acute and chronic exposures are the same because the same exposure occurs every day.

The breast milk consumption rate of 0.7 L/day and an infant body weight of 7.2 kg are from EPA's Exposure Factors Handbook (U.S. EPA, 1997).

It should be noted that factors such as body weight, race, and proximity of the subjects' residences to the facility were not addressed. These factors could have contributed to or detracted from the effects of Chemical C on the working mothers, and thereby on the infants of these mothers. Also, other potential sources of Chemical C exposure were not evaluated in this study. The study parameters and results are presented below in Table 6.

Table 6. Characteristics of Study Participants and Sample Results

Sample ID	Age (yrs)	Experience (yrs)	Activities	Result (mg/L)
PX-BMS-01	25	2	packaging	0.09

PX-BMS-02	19	<1	cleaning	0.07
PX-BMS-03	22	4	record keeping, monitoring	0.03
PX-BMS-04	28	7	maintenance	0.26

6.2   Worker Inhalation at a Processing Facility

In 2000, a study was conducted by Pesticide Formulators Inc. to evaluate potential exposures to Chemical C among workers in their Pest-X formulating plant (JMB, 2000). The study collected personal inhalation monitoring samples and analyzed them for Chemical C. The results were used to evaluate exposures among the workers in the Pest-X processing facility which uses a closed system to formulate Pest-X. Dermal exposures were not evaluated because a closed system is used that is fully automated and therefore eliminates the need to handle the material by hand.

Duplicate personal monitors were attached at the breathing zone of workers conducting typical activities in the processing plant where Pest-X is formulated with Chemical C as an inert ingredient. A total of 15 workers, who were involved in various activities, were monitored for a period of 8 hours. These activities included monitoring and adjusting the mixing tanks, as needed, recording data from metering devices and other record keeping functions, loading empty and filled Pest-X containers to and from the conveyer system, and miscellaneous cleaning and maintenance activities. These activities were conducted on a rotating basis by the various staff in the facility and all activities took place in the facility main processing room. Thus, specific workers could not be identified with a single discrete activity, and were assumed to be exposed to the levels of Chemical C that was in the air in that part of the facility (other parts of the facility included offices and storage areas not expected to be impacted by processing activities). Data on the physiological characteristics (i.e., height, weight, age, etc.) and work activities of the 15 workers was also collected and are provided in Table 7. Five of the workers were women and 10 were men ranging in age from 19 to 48 years, with experience levels ranging from <1 year to 20 years.

Sampling occurred on January 12, 2000. Personal sampling pumps ran at a volume of 500 mL/minute for the duration of the study. Replicate inhalation sampling devices were used for each worker to check the reproducibility of the analyses. At the end of the 8-hour monitoring period, the duplicate sampling cassettes from each worker were capped, labeled, and stored on dry ice during shipment to the analytical laboratory. Laboratory analysis occurred on January 26, 2000. A storage stability study had been conducted as part of a pilot project prior to the start of this study. The study indicated that Chemical C is stable during shipment and under the storage conditions used in the study.

Table 7. Characteristics of Workers

Replicate Number	Age (yrs)/Gender	Height (inches)	Weight (lbs)	Experience Level (yrs)	Activities
1	24/M	72	175	2	loading, cleaning
2	35/M	69	160	10	monitoring tanks, recordkeeping
3	32/F	63	130	5	recordkeeping
4	46/M	70	185	18	monitoring tanks, recordkeeping
5	22/F	65	125	1	loading, monitoring
6	19/M	75	180	<1	cleaning, maintenance
7	48/M	70	200	20	monitoring tanks, recordkeeping
8	33/M	71	190	8	loading
9	38/M	68	165	6	loading
10	31/F	67	150	5	maintenance, recordkeeping
11	20/M	74	210	<1	cleaning, maintenance, loading
12	41/F	63	120	10	monitoring tanks, recordkeeping, cleaning
13	32/M	69	178	7	
14	31/M	70	180	3	monitoring tanks, recordkeeping, maintenance
15	30/F	66	140	5	monitoring tanks, recordkeeping

SW 846, Method XXXX was used to analyze the samples. (U.S. EPA, 1986a). Analyses were performed by XYZ Laboratories in Nowhere, NJ. In addition to the personal monitoring samples, 2 blanks were analyzed. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study and before sampling began (JMB, 2000). The Plan outlined the objective and scope of the study and the QA/QC procedures that were followed by the laboratory. Laboratory fortified controls were prepared in duplicate at 2 levels (i.e., one at the limit of quantitation (LOQ; 0.1 $\mu g/m^3$) and one at 10 times the limit of quantitation (1 $\mu g/m^3$)). All of the blank samples contained non-detectable levels of Chemical C (Table 8). The LOQ was 0.1 $\mu g/m^3$ and the limit of detection (LOD) was 0.05 $\mu g/m^3$.

Table 8. Quality Control Data

Blanks	
Blank #1	ND (0.05 µg/m^3)
Blank #2	ND (0.05 µg/m^3)
Laboratory Fortifications	
LOQ level (0.1 µg/m^3) #1	98 % recovery
LOQ level (0.1 µg/m^3) #2	96 % recovery
10 x LOQ level (1 µg/m^3) #1	94 % recovery
10 x LOQ level (1 µg/m^3) #2	102 % recovery
Field Fortifications	
LOQ level (0.1 µg/m^3) #1	99 % recovery
LOQ level (0.1 µg/m^3) #2	95 % recovery
10 x LOQ level (1 µg/m^3) #1	100 % recovery
10 x LOQ level (1 µg/m^3) #2	101 % recovery

No amount of Chemical C above the detection limit of 0.05 µg/m^3 were observed in any of the personal monitoring samples collected (N=28) (Table 9). Therefore, an estimate of the ADD was calculated using the detection limit for the air samples because no measurable quantities were observed in the samples collected. Based on the limit of detection (0.05 µg/m^3), exposure to Chemical C was estimated to be <0.007 µg/kg/day.

Table 9. Monitoring Results

Replicate Number	Air Concentration ($\mu g/m^3$)
1	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
2	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
3	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
4	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
5	ND (0.05 $\mu g/m^3$) sample compromised
6	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
7	ND (0.05 $\mu g/m^3$) sample compromised
8	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
9	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
10	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
11	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
12	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
13	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
14	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)
15	ND (0.05 $\mu g/m^3$) ND (0.05 $\mu g/m^3$)

The average daily inhalation dose of Chemical C received by workers in the processing facility was estimated as follows:

$$APDR = C \times IR \times ET / BW$$

where:

APDR = acute potential dose rate(μg/kg/day);

C = concentration of Chemical C in air (<0.05 μg/m^3);

IR = inhalation rate (1.2 m^3/hr);

ET = exposure time (8 hrs/day); and

BW = body weight (70 kg).

Thus,

$$\text{APDR} = {<}0.007 \ \mu g/kg/day = ({<}0.05 \ \mu g/m^3 \times 1.2 \ m^3/hr \times 8 \ hr/d) / (70 \ kg)$$

The ADD was then calculated as:

$$\text{ADD} = \text{APDR} \times \text{EF} \times \text{ED} / \text{AT}$$

where:

ADD = average daily dose (μg/kg/day);

EF = exposure frequency (250 days/yr);

ED = exposure duration (25 yrs); and

AT = averaging time (25 years x 365 days/yr).

Thus,

$$\text{ADD} = {<}0.005 \ \mu g/kg/day = ({<}0.007 \ \mu g/kg/day \times 250 \ days/yr \times 25 \ yrs) / (25 \ yrs \times 365 \ days/yr)$$

The inhalation rate of 1.2 m^3/hr represents the rate for workers at a moderate activity level provided in the Exposure Factors Handbook (U.S. EPA, 1997). An assumed workday of 8 hrs was used, and a mean body weight of 70 kg was used (U.S. EPA, 1997).

It should be noted that the study only addresses potential exposure at a single facility that uses closed mixing and packaging. The results can not be applied to exposures at facilities using other types (e.g., open) of systems.

6.3   Exposure Among Residents Using Pest-X Indoors

6.3.1   Residential Handlers

A study was conducted in 2000 by (Smith et al. 2000a) of Pesticide Formulators Inc. The purpose of this study was to collect data that could be used to evaluate potential dermal and inhalation exposure to the Pest-X active ingredient and Chemical C during indoor residential application of Pest-X. The objective was to estimate high-end dermal and inhalation exposure among consumers who apply Pest-X in their homes.

A total of 5 adult volunteers were asked to use Pest-X according to the label directions. Each individual was asked to treat a single room, measuring approximately 100 ft^2, in different houses in California at the recommended application rate of 0.1 lb Pest-X/1,000 ft^2 (0.05 lb Chemical C/1,000 ft^2 based on 50% of Chemical C in Pest-X). Information on the physical characteristics of the individuals participating in the study as well as information on the housing types was collected via questionnaire as part of the pre study protocol. These data are summarized in Table 10.

Table 10. Characteristics of Study Participants and Treated Homes

Replicate #	1	2	3	4	5
Adult Volunteers					
Age (years)	34	42	36	44	50
Gender	F	M	M	F	M
Height (inches)	65	72	75	63	69
Weight (pounds)	120	190	220	140	170
Treated Houses					
Age (years)	12	26	5	22	18
Area Treated (ft^2)	100	105	95	102	106
Room Volume (ft^3)	800	900	760	820	854

The individuals applying Pest-X wore 100% cotton full body dermal dosimeters, cotton gloves, and dual personal inhalation monitors, clipped to their collars, in the breathing zone. Personal monitors were set to run at approximately 2 L/minute for the duration of the application process (i.e., 30 minutes). After application was complete, the personal monitoring cassettes were removed, capped, and placed on dry ice for shipment to the lab. Dermal dosimeters were removed, cut into pieces representing various body parts (i.e., arms, legs, torso), and placed in plastic bags for shipment to the laboratory. Gloves were also removed and sent to the lab. Residues on the face and neck were sampled using moistened gauze wipes measuring 100 cm^2. The wipes were placed in plastic bags and shipped on dry ice to the laboratory.

The analytical method used was developed and validated by Pest-Labs Inc. in Orange, California. The method is titled PS 280 R. Replicate inhalation sampling devices were used for each worker to check the reproducibility of the analyses. Likewise, duplicate dosimeters samples were analyzed (i.e., both legs, both arms, etc.). Negative (blank) control samples and field spikes were also analyzed. Field fortified controls were prepared for both inhalation and dermal samples at 3 concentrations (at LOQ, 10 times LOQ and 100 times LOQ). The results of the field fortifications indicate that recovery of Chemical C was within an acceptable range (i.e., > 90%). Thus, no correction for recovery was required. Also, blank samples (N=2) were consistently below the limit of detection (LOD). For air samples, the LOD was 0.01 $\mu g/m^3$ and the LOQ was 0.05 $\mu g/m^3$. For the dermal dosimetry samples, the LOD was 0.0005 mg/cm^2, and the LOQ was 0.001 mg/cm^2. Table 11 provides the quality control data for air and dosimeter samples.

Table 11. Quality Control Data

Air Samples	
Blank #1	ND (0.01 $\mu g/m^3$)
Blank #2	ND (0.01 $\mu g/m^3$)
LOQ level (0.05 $\mu g/m^3$) #1	98 % recovery
LOQ level (0.05 $\mu g/m^3$) #2	96 % recovery
10 x LOQ level (0.5 $\mu g/m^3$) #1	94 % recovery
10 x LOQ level (0.5 $\mu g/m^3$) #2	94 % recovery
100 x LOQ level (5 $\mu g/m^3$) #1	94 % recovery
100 x LOQ level (5 $\mu g/m^3$) #2	102 % recovery
Dosimetry Samples	
Blank #1	ND (0.0005 mg/cm^2)
Blank #2	ND (0.0005 mg/cm^2)
LOQ level (0.001 mg/cm^2) #1	99 % recovery
LOQ level (0.001 mg/cm^2) #2	95 % recovery
10 x LOQ level (0.01 mg/cm^2) #1	95 % recovery
10 x LOQ level (0.01 mg/cm^2) #2	95 % recovery
100 x LOQ level (0.1 mg/cm^2) #1	100 % recovery
100 x LOQ level (0.1 mg/cm^2) #2	101 % recovery

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study and before sampling began (Smith et al. 2000a) . The Plan outlined

the objective and scope of the study and the QA/QC procedures that were followed by the laboratory. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

The results of the monitoring study are provided in Table 12. Residues of Chemical C were observed only on the glove dosimeters indicating that potential dermal exposure occurs only to the hands. The concentration of Chemical C on the gloves ranged from 0.0075 to 0.015 mg/cm^2. Residues of Chemical C in the personal inhalation monitors ranged from 0.1 to 0.2 µg/m^3.

Table 12. Results

Replicate		Concentration of Chemical C
Air Samples		
1		0.10 µg/m^3; 0.12 µg/m^3
2		0.18 µg/m^3; 0.20 µg/m^3
3		0.14 µg/m^3; 0.15 µg/m^3
4		0.10 µg/m^3; 0.12 µg/m^3
5		0.13 µg/m^3; 0.15 µg/m^3
Dosimeter Samples		
1	arms	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	legs	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	torso	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	face/neck	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	hands	0.0075 mg/cm^2; 0.0078 mg/cm^2
2	arms	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	legs	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	torso	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	face/neck	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	hands	0.015 mg/cm^2; 0.013 mg/cm^2
3	arms	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	legs	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	torso	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	face/neck	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	hands	0.0075 mg/cm^2; 0.0077 mg/cm^2
4	arms	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	legs	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	torso	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	face/neck	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	hands	0.0090 mg/cm^2; 0.0098 mg/cm^2

5	arms	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	legs	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	torso	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	face/neck	ND (0.0005 mg/cm^2); ND (0.0005 mg/cm^2)
	hands	0.0085 mg/cm^2; 0.0088 mg/cm^2

Based on the sampling results, dermal and inhalation exposures were estimated using the range of detected values and standard exposure factors. Dermal exposure was estimated to range from 0.009 to 0.017 mg/kg/day using a surface area of the hands of 800 cm^2, an absorption rate of 10%, and a body weight of 70 kg. This is based on values in the Exposure Factors Handbook (U.S. EPA, 1997) and the concentrations of Chemical C observed on the dermal dosimeters. The absorption factor was based on a study using pigskin to simulate absorption through human skin (Pesticide Formulators Inc., 2000). The absorbed dermal Dose was estimated as follows:

$$APDR = C \times SA \times Abs / BW$$

where:

$APDR$ = acute potential dose rate (mg/kg/day);

C = concentration of Chemical C on dosimeters (0.0075 to 0.015 mg/cm^2);

SA = surface area of the skin (800 cm^2/day);

Abs = absorption fraction of Chemical C (0.1); and

BW = body weight (70 kg).

Thus,

$APDR = 0.009$ to 0.017 mg/kg/day $= (0.0075$ to 0.015 mg/cm^2 x 800 cm^2/day) x $(0.1 / 70$ kg$)$

The ADD was then calculated as:

$$ADD = APDR \times EF \times ED / AT$$

where:

ADD = average daily dose (mg/kg/day);

EF = exposure frequency (12 days/yr);

ED = exposure duration (30 yrs); and

AT = averaging time (30 yrs x 365 days/yr).

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Thus,

ADD = 0.00028 to 0.00056 = (0.009 to 0.017 mg/kg/day x 12 days/yr x 30 yrs) / (30 yrs x 365
days/yr)

Inhalation exposure was estimated to range from 0.0007 to 0.0014 µg/g/day, using assumptions from the Exposure Factors Handbook (U.S. EPA, 1997) (i.e., 1 m^3/hr inhalation rate for light activity level and a body weight of 70 kg) and an exposure time of ½ hour.

$$APDR = C \times IR \times ET$$

where:

APDR = acute potential dose rate (µg/kg/day);
C = concentration of Chemical C in air (0.1 to 0.2 µg/m^3);
IR = inhalation rate (1 m^3/hr);
ET = exposure time (½ hr/day); and
BW = body weight (70 kg).

Thus,

APDR = 7.0×10^{-7} to 1.4×10^{-6} mg/kg/day = (0.1 to 0.2 µg/m^3 x 1 m^3/hr x ½ hr/day) / (70 kg)

The ADD was then calculated as:

$$ADD = APDR \times EF \times ED / AT$$

where:

ADD = average daily dose (mg/kg/day);
EF = exposure frequency (12 days/yr);
ED = exposure duration (30 yrs); and
AT = averaging time (30 yrs x 365 days/yr).

Thus,

$$ADD = 2.4 \times 10^{-8} \text{ to } 4.7 \times 10^{-8} \text{ (mg/kg/day)} = (7.0 \times 10^{-7} \text{ to } 1.4 \times 10^{-6} \text{ mg/kg/day} \times 12$$
$$\text{days/yr} \times 30 \text{ yrs)} / (30 \text{ yrs} \times 365 \text{ days/yr})$$

It should be noted that this study was limited to 5 homes and may not be representative of all housing types or geographic regions. There is also uncertainty associated with the absorption factor used. This factor was based on a study using pigskin to simulate absorption through human skin (Pesticide Formulators Inc., 2000).

6.3.2 Residential Postapplication Exposure

In another study conducted by Smith et al. (2000b), residential air was monitored for Chemical C after indoor treatment with Pest-X. The data were used to evaluate the dissipation kinetics of Chemical C in the indoor environment and to evaluate potential inhalation exposures. The objective of the study was to estimate potential inhalation exposures to Chemical C among children residing in homes where Pest-X is used for crack and crevice treatment. Although the data may also be used to address adult exposures, the focus of the study was on children because they were assumed to be the most sensitive population [if toxicological data indicates Chemical C is a reproductive toxicant, this assumption may have to be modified, i.e., and aggregate dose for adults may also be required]. Exposure on a body weight basis was expected to be higher among children than adults. The study used the detection limit for Chemical C in air to calculate inhalation exposures because no measurable concentrations of Chemical C were observed in air.

Stationary monitors were placed in 5 locations in a 100 ft^2 room, within the breathing zone of a child (a distance of 1 meter from the floor). The monitors ran at a rate of 10 L/minute for a 4-hour period with sampling cassettes being changed each hour. At the end of each 1-hour sampling period, sampling cassettes were capped, labeled, and stored on dry ice until shipment to the analytical laboratory. A total of 5 homes in California were used in the study. Data on the housing characteristics of the 5 homes were not provided in the study.

The analytical method used was developed and validated by Pest-Labs Inc. in Orange, California. The method is titled PS 280 R. Replicate inhalation sampling devices were used for each sampler to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. Field fortified controls were prepared at 2 concentrations (at LOQ, and 10 times LOQ). The results of the field fortifications indicate that recovery of Chemical C was within an acceptable range (i.e., > 90%). Thus, no correction for recovery was required. Also,

blank samples (N=2) were consistently below the limit of detection (LOD). The LOD was 0.006 $\mu g/m^3$ and the LOQ was 0.01 $\mu g/m^3$. Table 13 provides the quality control data for the samples.

Table 13. Quality Control Data

Air Samples	
Blank #1	ND (0.006 µg/m³)
Blank #2	ND (0.006 µg/m³)
LOQ level (0.006 µg/m³) #1	98 % recovery
LOQ level (0.006 µg/m³) #2	96 % recovery
10 x LOQ level (0.06 µg/m³) #1	94 % recovery
10 x LOQ level (0.06 µg/m³) #2	94 % recovery

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study and before sampling began (Smith et al. 2000b). The Plan outlined the objective and scope of the study and the QA/QC procedures that were followed by the laboratory. Replicate inhalation sampling devices were used to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

The results of the analyses indicate that no residues of Chemical C above the detection limit of 0.006 µg/m³ were observed. Based on the limit of detection for Chemical C and the recommended inhalation rate for children as cited in EPA's Exposure Factors Handbook (U.S. EPA, 1997), inhalation exposure to Chemical C among children was estimated to be <0.003 µg/kg/day, as follows.

$$APDR = C \times IR / BW$$

where:

APDR = acute potential dose rate (µg/kg/day);
C = concentration of Chemical C in air (<0.006 µg/m³);
IR = inhalation rate (8.3 m³/day); and
BW = body weight (15 kg).

Thus,

$APDR = < 3 \times 10^{-6}$ mg/kg/day = (<0.006 µg/m³ x 8.3 m³/day) / (15 kg) * 1 mg/1000 µg

The ADD was then calculated as:

$$ADD = APDR \times EF \times ED / AT$$

where:

ADD   =   average daily dose ($\mu g/kg/day$);

EF   =   exposure frequency (365 days/yr);

ED   =   exposure duration (1 yr); and

AT   =   averaging time (1 year x 365 days/yr).

Thus,

ADD = <0.003 $\mu g/kg/day$ = (<0.003 $\mu g/kg/day$ x 365 days/yr x 1yr) / (1 yr x 365 days/yr)

For this scenario, the acute and chronic exposures are the same because the same exposure occurs every day.

The inhalation rate of 8.3 m^3/day represents a mean daily rate for 3-5 year old children (U.S. EPA, 1997), and a body weight of 15 kg represents the weight for a 3-year old child (U.S. EPA, 1997). Because both the acute and chronic dose estimates were based on 24 hour a day exposure to Chemical C, and the limit of detection was greater than the level present in the study homes, these may be considered conservative, high-end estimates.

It should be noted that this study was limited to 5 homes in California. These homes may not be entirely representative of all U.S. homes, i.e., the confidence in the representativeness of the study results is low.

6.4   Department of Defense National Groundwater Study

In 1995, the United States Department of Defense (DoD) conducted a study (DoD, 1995) to examine levels of a variety of chemicals in the nation's groundwater. This study was identified in a literature search conducted by Inert Manufacturers Inc. intended to locate information on the levels of Chemical C in the environment. A copy of the study was obtained from W.E. Norton, Riverton, GA, the contractor to DoD for the study. The data from the DoD Groundwater Study were used by Inert Manufacturers Inc. to estimate exposure to Chemical C from ingestion of

groundwater among children in an exposure assessment report. Although dermal exposure and inhalation from household use of groundwater were also considered to be potential routes of exposure to Chemical C, exposure via these routes were not presented in the assessment, because ingestion of drinking water was considered to be the primary route of exposure. Also, the exposure assessment focused on children (ages 3-5 years). Exposure estimates for other age groups were not provided.

A total of 563 groundwater samples were collected from monitoring wells across the country. In general, existing monitoring wells from previous studies on Federal (i.e., DoD) facilities were used. Samples (500 mL) were drawn from the wells, placed in amber bottles, and shipped to the laboratory on dry ice for analysis. DoD Method PX-346 for the analysis of chemicals in groundwater was used to analyze the samples for Chemical C and other compounds. This method uses HPLC to quantify Chemical C.

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study and before sampling began (DoD, 1995). The Plan outlined the objective and scope of the study and the QA/QC procedures that were followed by the laboratory. Replicate inhalation sampling devices were used for each worker to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

The monitoring results from the study are summarized as follows:

Chemical C was detected in 486 of the 563 groundwater samples analyzed. The detection limit was 0.1 µg/L;

The mean concentration was 0.25 µg/L; and

The range of detected values was 0.11 to 0.56 µg/L.

Using the mean concentration of 0.25 µg/L, a high-end daily ingestion rate of 1 L/day and a body weight of 15 kg, the dose to a 3-year old child would be 0.017 µg/kg/day, as shown below.

$$APDR = C \times IR / BW$$

where:

        APDR   =   acute potential dose rate daily dose (μg/kg/day);

        C   =   mean concentration of Chemical C in groundwater (0.25 μg/L);

        IR   =   ingestion rate of water (1 L/day); and

        BW   =   body weight (15 kg).

Thus,

$$APDR = 1.7 \times 10^{-5} \text{ mg/kg/day} = (0.25 \text{ } \mu g/L \times 1 \text{ L/day}) / (15 \text{ kg}) * 1 \text{ mg}/1000 \text{ } \mu g$$

The average daily dose (ADD) for longer-term exposure was then calculated as:

$$ADD = APDR \times EF \times ED / AT$$

where:

        APDR   =   acute potential dose rate (μg/kg/day), adjusted for mean daily water consumption = C x IR / BW

                      =   0.4 L/day x 0.25 μg/L / 15 kg

                      = 6.7×10^{-3} μg/kg/day = 6.7×10^{-6} mg/kg/day

and where:

        ADD   =   average daily dose (mg/kg/day);

        EF   =   exposure frequency (365 days/yr);

        ED   =   exposure duration (3 yrs); and

        AT   =   averaging time (3 yrs x 365 days/yr).

Thus,

$$ADD = 6.7 \times 10^{-6} \text{ mg/kg/day} = (6.7 \times 10^{-6} \text{ mg/kg/day} \times 365 \text{ days/yr} \times 3 \text{ yrs}) / (3 \text{ yrs} \times 365 \text{ days/yr})$$

For this scenario, the acute exposure is slightly higher than the chronic because the upper-percentile estimate of 1 L/day tap water consumption was used for the acute estimate and the lower average

public water intake was used for the chronic exposure estimate for children under 10 years (Child-Specific Exposure Factors Handbook, External Review Draft, 2001).

It should be noted that the monitoring study concentrated sampling efforts near Federal facilities. It is uncertain whether these locations are representative of the nation as a whole. Also, because other potential routes of exposure (i.e., dermal and inhalation) were not assessed, the exposure estimates provided by this study may underestimate the total dose from water.

6.5   Ongoing Studies

Several ongoing monitoring studies are ongoing, and when complete, will aid in estimating exposure to Chemical C from pathways not evaluated in this report. For example, Inert Manufacturers Inc. has recently initiated a monitoring program that will measure Chemical C in the water discharges from our facility. To date, a total of 12 samples have been collected and analyzed. The data have not yet been fully validated and represent only a small fraction of the data that will be collected under this effort. However, preliminary results indicate that surface water releases are very low (i.e., at or below the limit of detection). It is expected that a full report on these data will be available by the end of the calendar year. In addition, an air monitoring program in the vicinity of Inert Manufacturers Inc. is due to commence within the coming year. Samples will be collected at 16 downwind locations via high volume stationary air monitors. The results of this monitoring effort are expected in late 2002. These data will be used to validate the ISCLT modeling that was done for the same facility. Similar water and air studies are underway at Pesticide Formulators Inc., a processor of Chemical C. These data are expected to be released in early 2002.

7.   MODELING DATA

7.1   Use of ISCLT to Model Dispersion of Fugitive Emissions of Chemical C from Manufacturing Plant

Under the Toxic Chemical Release Inventory (TRI) program, releases from the Pest-X formulating plant are reported annually on the Form R. Point source releases from this facility were modeled using the Industrial Source Complex-Long Term (ISCLT) Model in the PC-based, Graphical Exposure Modeling System (PCGEMS), V2.05, 1995. The results of the ISCLT estimate the concentration of Chemical C and the corresponding exposure to the local population associated with these emissions.

Note that the ISCLT model has been validated with monitoring data that are directly relevant for the scenario of interest (Modeler, 1996). Also, the model has been through a formal peer review process (Reviewer, 1998). PCGEMS is included in the Exposure Models Library and Integrated Model Evaluation System, a CD-ROM issued by EPA's Office of Research and Development. The CD-ROM is a collection of EPA tools for exposure and risk assessment. The model algorithm and assumptions are discussed in detail on EPA's web site, and therefore, are not repeated here.

The following inputs were used to model the stack emissions from the facility:

Stack Height   -   61.2m
Exit Velocity   -   2 m/s
Diameter   -   5.0 m
Source Emission   -   45.36 kg/year(1.44×10^{-3}g/s)

The point source emissions from this facility were modeled as a single point-source emission from the facility. All of the point source air emissions at this facility are from facility building exhaust fans that vent to the atmosphere from the facility roof. The stack height of 61.2 meters is the height of the facility. The exit velocity is the actual value measured at the vents.

The combination of all of the point air emissions from this facility yielded an effective stack diameter of 5.0 meters. This was determined by adding all of the exhaust vent cross-section areas. If this total area was the area of a circle, the diameter of that circle would be 5.0 meters. The source emission is based on the 100 pounds per year estimated on the Form R, plus the fact that the facility operates 24 hours per day, 365 days per year. Default model inputs were used for all other parameters.

The output from the ISCLT model run is included as Appendix B of this report. As shown in the output, the maximum concentration calculated by the ISCLT model was 4.74×10^{-4} µg/m³. The maximum dose calculated by the ISCLT model was 1.36×10^{-7} mg/kg/day.

It should be noted that the model accounts for the contribution of point source air emissions from only one facility. It does not consider Chemical C inputs from other sources. The values estimated are likely not representative of the additive effects of other facilities in nearby locations. The model also does not account for the presence of other chemicals in the atmosphere, and their possible additive effects on the toxicity of Chemical C.

7.2 Dermal and Hand-to-mouth Exposure Among Children in Pest-X-Treated Indoor Environments

Smith et al. (2000c) also conducted modeling to estimate residential exposure to chemical C after indoor treatment with Pest-X. The purpose of the modeling exercise was to provide a conservative estimate of dermal and hand-to-mouth exposure based on the application rate and default exposure assumptions for hard surfaces. Exposures were assessed on the day of application (i.e., assumes no dissipation) to provide upper percentile estimates, as recommended in EPA's Standard Operating Procedures (SOPs) for Residential Exposure Assessment (U.S. EPA, 2001). Specifically, Sections 8.2.2 and 8.2.4 of the SOPs were followed in modeling these exposures. Because the SOPs are not a computerized model, but a document prepared by EPA's Office of Pesticide Programs that provides algorithms and assumptions for various pesticide exposure scenarios, the modeling was conducted using Excel spreadsheets created by Pesticide Formulators Inc. Note that the SOPs document has been developed and internally reviewed by various EPA offices and the Science Advisory Panel, and is available from U.S. EPA (EPA, 2001).

The following algorithms and assumptions were used in assessing absorbed dermal dose dermal and non-dietary ingestion exposure.

For dermal exposure:

$$\text{Dermal APDR} = \text{ISR} \times \text{TC} \times \text{Abs} \times \text{ET} / \text{BW}$$

where:

Dermal APDR	=	acute potential dose rate (mg/kg/day);
ISR	=	indoor surface residue (mg/cm^2; ISR = AR x 4.54E5 mg/lb x 1.08E-3 ft^2/cm^2 x FA or 0.05 lbs/1,000 ft^2 x 4.54E5 mg/lb x 1.08E-3 ft^2/cm^2 x 0.1 = 0.0025 mg/cm^2);
AR	=	application rate (0.1 lbs Pest-X or 0.05 lbs of Chemical C/1,000 ft^2);
FA	=	fraction available for dislodging (0.1);
TC	=	transfer coefficient (6,000 cm^2/hr; any time duration);
Abs	=	absorption fraction (0.1);
ET	=	exposure time on hard surfaces (4 hr/day); and
BW	=	body weight (15 kg).

Thus,

Dermal APDR = 0.4 mg/kg/day = (0.0025 mg/cm^2 x 6,000 cm^2/hr x 0.1 x 4 hrs/day) / (15 kg)

The assumptions were as follows: 10% of the application rate is available for dislodging, the transfer coefficient is 6,000 cm^2/hr for toddlers, and the exposure time is 4 hours/day on hard surfaces (U.S. EPA, 2001). Exposure is assessed on the day of application (i.e., no dissipation). Body weight is assumed to be 15 kg, and absorption is assumed to be 10% for Chemical C.

For Non-Dietary Ingestion:

Non-Dietary Ingestion APDR = ISR x SA x EF x SEF x ET / BW

where:

Non-Dietary Ingestion APDR	=	Acute potential dose rate (mg/kg/day);
ISR	=	indoor surface residue (mg/cm^2; ISR = AR x 4.54E5 mg/lb x 1.08E-3 ft^2/cm^2 x FA or 0.05 lbs/1,000 ft^2 x 4.54E5 mg/lb x 1.08E-3 ft^2/cm^2 x 0.1 = 0.0025 mg/cm^2);
SA	=	skin surface area (20 cm^2/event);
EF	=	event frequency (20 events/hr for acute; 9.5 events/hr for longer term);
SEF	=	saliva extraction fraction (0.5);
ET	=	exposure time (4 hr/day); and
BW	=	body weight (15 kg).

Thus,

Non-Dietary Ingestion APDR = 0.13 mg/kg/day = (0.0025 mg/cm^2 x 20 cm^2/ev x 20 ev/hr x 0.5 x 4 hr/day) / (15 kg)

The Dermal ADD was then calculated as:

Dermal ADD = Dermal APDR x EF x ED / AT

where:

ADD	=	absorbed average dermal dose rate (mg/kg/day);
EF	=	exposure frequency (365 days/yr);
ED	=	exposure duration (1 yr); and

$$AT \quad = \quad \text{averaging time (1 yr x 365 days/yr).}$$

Thus,

$$\text{Dermal ADD} = 0.4 \text{ mg/kg/day} = 0.4 \text{ mg/kg/day x 365 days/yr x 1 yr/1 yr x 365 days/yr}$$

For this scenario, the acute and chronic exposures are the same because the exposure is assumed to occur every day. It should be noted that the ADD, for the purposes of this Tier I assessment, assumes that residue levels remain the same for the duration of exposure. This may be an overestimate, as residues may will dissipate between treatments.

For Non-Dietary Ingestion,

$$\text{Non-Dietary Ingestion ADD} = \text{Non-Dietary Ingestion APDR x EF x ED / AT}$$

where:

Non-Dietary Ingestion APDR
= acute potential dose rate for longer-term exposure [note frequency has been reduced for to the long-term average hand-mouth events];
= ISR x SA x EF x SEF x ET / BW;
= 0.0025 mg/cm^2 x 20 cm^2/ev x 9.5 ev/hr x 0.5 x 4 hr/day / 15 kg; and
= 0.063 mg/kg/day

$$\text{ADD} = \text{APDR x EF x ED / AT}$$

where:

Non-Dietary Ingestion ADD	=	average nondietary daily dose (mg/kg/day);
Non-Dietary Ingestion APDR	=	nondietary Hand-to-Mouth acute potential dose rate (mg/kg/day);
EF	=	exposure frequency (365 days/yr);
ED	=	exposure duration (1 yr); and
AT	=	averaging time (1 yr x 365 days/yr).

Thus,

$$\text{ADD} = 0.063 \text{ mg/kg/day} = 0.063 \text{ mg/kg/day x 365 days/yr x 1 yr / 1 yr x 365 days/yr}$$

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For the non-dietary ingestion, or hand-to-mouth scenario, the acute exposure is higher than the average estimate due to the assumption of a higher rate of exposure frequency. It should be noted that the ADD, for the purposes of this Tier I assessment, assumes that residue levels remain the same for the duration of exposure. This may be an overestimate, as residues ~~may~~ dissipate between treatments. Also, there were no use frequency data, which, if available, might refine the exposure frequency estimate. Surface area is assumed to be 20 cm^2/event (hands) for toddlers; frequency is 20 events/hour for the short-term and 9.5 events/hr for longer term estimates; saliva extraction factor is 50% (U.S. EPA, 2001) . The exposure time is 4 hours/day and body weight is assumed to be 15 kg (U.S. EPA, 2001). Exposure is assessed on the day of application (i.e., no dissipation).

The scenarios assessed here assume the pesticide residues are transferred to the skin of a toddler (3-year old child) who comes into contact with areas treated with Pest-X, such as floors and counter tops during play activities. Exposure occurs from dermal uptake and/or hand-to-mouth contact.

Based on this modeling exercise, acute, or short-term postapplication dermal exposure among 3-year old children was estimated to be 0.4 mg/kg/day. Non-dietary (hand-to-mouth) short-term exposure was 0.13 mg/kg/day and longer-term was 0.063 mg/kg/day. Uncertainties occur from assumptions regarding dissipation and transfer of chemical residues. The transfer coefficient is based on data for adults (scaled to children) (Cal EPA, 1996). Also, uncertainties exist related to skin surface area, hand-to-mouth frequency, and absorption factor. The absorption fraction is based on a single study using pigskin to evaluate dermal uptake of Chemical C. According to U.S. EPA (2001), the exposure estimates generated by this method are assumed to represent high-end exposures. Because a combination of central tendency and high-end, conservative inputs were used, the estimates are believed to be upper percentile values.

7.4   Aggregate Exposure to Chemical C Among Children

In a recent report, SP Multiple (2001), a contractor to Inert Manufacturers Inc., assessed aggregate exposure for small children. The purpose of the assessment was to evaluate total potential exposure to Chemical C among children from multiple pathways. The selection of the 3-year old to represent a toddler and therefore a worst-case, multiple-route exposure scenario was based on analysis of all available monitoring and modeling exposure data. The estimated exposures which have been presented earlier in this assessment were examined and for each age group (infants, children, adults) those exposures which were likely to co-occur (see Table 5). It is possible that adults, such as commercial pesticide operators, may utilize several times the amount of product per

day that was applied in the monitoring study. However, even when such adults' exposure during application was considered, the highest total exposure was found for the toddlers. Infants are primarily exposed through water, breast milk, and inhalation, and there is uncertainty as to potential dermal exposure for a crawling baby. Therefore, this analysis summed the estimated doses to a 3-year old child from various exposure pathways. The inputs used for assessing aggregate exposure are the exposure estimates for 3-year old children presented in the various monitoring and modeling studies previously summarized in this exposure assessment report..

Because the toxicity endpoints for Chemical C are the same for dermal, oral, and inhalation exposure, doses from these pathways could be summed to estimate the total dose to children. Estimated doses from the following exposure pathways were added to estimate the aggregate short-term dose:

> ingestion of groundwater;
> indoor postapplication inhalation;
> indoor postapplication dermal; and
> indoor postapplication non-dietary ingestion (i.e., hand-to-mouth).

Inhalation of Chemical C in fugitive emissions was not included in the aggregate exposure calculations for children because such exposures were negligible; compared to those based on other exposure pathways. Also, in order to be conservative, 3-year old children were assumed to spend their entire day in an indoor environment (i.e., inhaling postapplication indoor air residues).

The assumptions used in the assessment are as follows:

> inhalation exposure among 3-year old residential children is 3.0×10^{-6} mg/kg/day, based on indoor air concentrations at the detection limit;

> dermal exposure among residential children is 0.4 mg/kg/day, based on a modeling study intended to calculate upper-percentile estimates;

> non-dietary ingestion exposure among residential children is 0.13 mg/kg/day (APDR) and 0.063 mg/kg/day (ADD), based on a modeling study intended to calculate upper-percentile estimates; and

> drinking water ingestion exposure is 1.7×10^{-5} mg/kg/day (APDR) and 6.7×10^{-6} mg/kg/day (ADD) based on the mean groundwater concentration of Chemical C.

Thus, the acute aggregate dose was estimated to be 0.53 mg/kg/day, and the chronic/long-term aggregate dose was 0.46 mg/kg/day from all pathways with dermal contact accounting for the majority of the exposure, as follows:

$$ADD = \text{Inhalation Dose} + \text{Dermal Dose} + \text{Non-dietary Dose} + \text{Dietary (water) Dose}$$

where:

$$\text{Acute Aggregate Dose} =$$
$$0.53 \text{ mg/kg/day} = 3E\text{-}6 \text{ mg/kg/day} + 0.4 \text{ mg/kg/day} + 0.13 \text{ mg/kg/day} + 1.7E\text{-}5 \text{ mg/kg/day}$$

$$\text{Chronic/long-term Aggregate Dose} =$$
$$0.46 \text{ mg/kg/day} = 3E\text{-}6 \text{ mg/kg/day} + 0.4 \text{ mg/kg/day} + 0.063 \text{ mg/kg/day} + 6.7 E\text{-}6 \text{ mg/kg/day}$$

It should be noted that this exposure scenario is for a 3-year old child who may be exposed to Chemical C via multiple pathways in a single day. It assumes that the child lives in a home treated with Chemical C and that on the day the child is exposed to postapplication residues of Chemical C via inhalation, dermal contact with hard surfaces, and hand-to-mouth contact, the child also consumes contaminated groundwater. The purpose was to generate a conservative estimate of aggregate exposure using primarily high-end exposure estimates from the various pathways for the purpose of a screening level risk assessment for Chemical C. The uncertainties associated with this assessment stem from the use of high-end exposure estimates for all pathways. It is not clear that exposure in a single individual from all pathways would occur simultaneously at the high-end of the distribution.

7.5   Ongoing Studies

No modeling efforts are ongoing or planned at this time.

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APPENDIX A

TRI REPORTS

Appendix A1. TRI Reporting Summary - Inert Manufacturers Inc.

			# days/year release occurs
Specify units: ☐ lbs Or kgs			
A.	On-site Air Release		
	Fugitive	900	365
	Stack	100	365
B.	Water Releases from Site		
Water Releases		NA	
	Receiving water name:		
C.	On-Site Land Releases		
	Landfill	NA	
	Land Treatment/ Land Amendment	NA	
	Surface Impoundment	NA	
	Underground Injection	NA	
	Other (specify)	NA	
D.	Off-site Transfers		
D1.	Transfer to Publicly Owned Treatment Works (POTWs)	NA	

POTW Name:

Street Address:

City: County:

State: Zip Code:

NPDES number:

D2.   Transfers To Other Off-Site Locations

Incineration   NA   _____

Wastewater Treatment   NA   _____
(Excluding POTW)

Underground Injection   NA   _____

Hazardous Waste (RCRA Subtitle   100   1
C) landfill

Other landfill   NA   _____

Recycle or Recovery   NA   _____

Unknown or Other   NA   _____

Appendix A2. TRI Reporting Summary - Pesticide Formulators Inc.

Specify units: ☐ lbs Or kgs	Estimated Total Annual Releases	# days/year release occurs
A. On-site Air Release		
Fugitive	5000	250
Stack	NA	
B. Water Releases from Site		
Water Releases	5000	250
Receiving water name:		
C. On-Site Land Releases		
Landfill	NA	
Land Treatment/ Land Amendment	NA	
Surface Impoundment	NA	
Underground Injection	NA	
Other (specify)	NA	
D. Off-site Transfers		
D1. Transfer to Publicly Owned Treatment Works (POTWs)	NA	

POTW Name:

Street Address:

City: County:

State: Zip Code:

NPDES number:

D2.   Transfers To Other Off-Site Locations

   Incineration   NA   _____

   Wastewater Treatment   NA   _____
   (Excluding POTW)

   Underground Injection   NA   _____

   Hazardous Waste (RCRA   NA   _____
   Subtitle C) landfill

   Other landfill   NA   _____

   Recycle or Recovery   _____   _____

   Unknown or Other   NA   _____

APPENDIX B

ISCLT Model Run Output

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                    EXPOSURE AND RISK ESTIMATION
                         FROM ISCLT001

                 1990 Population - Block Group Level

        Cumulative Population Exposed by Concentration Level
                 ISCLT Source Name: SOURCE1

                                      CUMULATIVE
         CONCENTRATION LEVEL       POPULATION EXPOSED
             (UG/M3)               (PERSONS)    (%)
         ------------------        ------------------
                   1.39E-05             190   15.24
         1.39E-05 - 1.00E-05           190   15.24
         1.00E-05 - 1.07E-06         1,247  100.00

         Maximum Calculated Concentration: 4.74E-04




        Cumulative Population Exposed by Concentration Level
                 ISCLT Source Name:    TOTAL

                                      CUMULATIVE
         CONCENTRATION LEVEL       POPULATION EXPOSED
             (UG/M3)               (PERSONS)    (%)
         ------------------        ------------------
                   1.39E-05             190   15.24
         1.39E-05 - 1.00E-05           190   15.24
         1.00E-05 - 1.07E-06         1,247  100.00

         Maximum Calculated Concentration: 4.74E-04




         Cumulative Population Exposed by LADD Level
                 ISCLT Source Name: SOURCE1

                                      CUMULATIVE
           LADD LEVELS             POPULATION EXPOSED
          (mg/kg/day)              (PERSONS)    (%)
         ------------------        ------------------
                   3.97E-09             190   15.24
         3.97E-09 - 1.00E-09           784   62.87
         1.00E-09 - 3.07E-10         1,247  100.00

         Maximum Calculated Dose: 1.36E-07
```